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EXAMINER
BOWMAN, AMY HUDSON

ART UNIT	PAPER NUMBER
1635	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/579,662	MOR ET AL.	
	Examiner	Art Unit	
	AMY BOWMAN	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 August 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-9,19 and 21-27* is/are pending in the application.

4a) Of the above claim(s) *4,7,19 and 21-27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 2, 5, 6, 8, and 9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *5/17/06* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/25/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election with traverse of group II, in the reply filed on 8/28/08 is acknowledged. The traversal is on the ground(s) that the method of utilizing an antisense oligonucleotide of group I because examination can be made without serious burden because the groups are classified in the same class and subclass; and both inhibitors have an antisense strand. This is not found persuasive because class 514, subclass 44 is very large and encompasses a huge multitude of inventions. To search for one of the inventions would not necessarily return art against the other simply based upon the same classification. Furthermore, although each of the inhibitory compounds has an antisense strand, antisense oligonucleotides and siRNA molecules act via completely different mechanisms and have different design parameters as a result. Antisense oligonucleotides act via the recruitment of RNAse H or via steric hindrance, for example, whereas siRNA molecules interact with a complex protein complex, RISC. To search for a method of using one of the molecules would not necessarily return art against the other. Furthermore, there is nothing of record to show that they are obvious variants of each other.

It is noted that claim 7 was inadvertently indicated as a linking claim in the office action mailed on 6/23/08. The examiner informed applicant's representative on 11/25/08 that claim 7 is not a linking claim because claim 7 is directed to a method of utilizing an antibody and was correctly restricted into its own group, group III. Claim 1 links the inventions of groups I-III and claims 2, 8, and 9 are included in group II and

examined herein. Therefore, the correct claims that will be examined herein as group II are claims 1, 2, 5, 6, 8, and 9, directed to a method of utilizing a siRNA.

The requirement is still deemed proper and is therefore made FINAL.

Claims 4, 7, 19, and 21-27; as well as the subject matter of the claims that is not directed to the elected invention, is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 8/28/08. It is noted that "oligonucleotide" is withdrawn from claim 2, as applicant has elected subject matter directed to siRNA methods. Therefore, the claim will be examined to the extent to which it reads on oligoribonucleotides.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 6/25/07 has been considered by the examiner.

Sequence Compliance

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 because there are sequences in the figures that do not contain a SEQ ID NO. Although the brief description of the figures in the specification beginning at page 8 sets forth SEQ ID NOs for the sequences in the figures, the figures have

Figure 1A and 1B, as well as Figure 3A and 3B. However, the specification only refers to "Figure 1" and "Figure 3" and one SEQ ID NO for each.

A complete response to this office action must correct the defects cited above regarding compliance with the sequence rules and a response to the action on the merits which follows.

The aforementioned instance of failure to comply is not intended as an exhaustive list of all such potential failures to comply in the instant application. Applicants are encouraged to thoroughly review the application to ensure that the entire application is in full compliance with all sequence rules. This requirement will not be held in abeyance.

Drawings

The drawings are objected to because they contain sequences that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2), but each sequence does not contain a SEQ ID NO., as explained in the “Sequence Compliance” section above. Corrected drawing sheets in compliance with 37 CFR 1.121(d) or amendment to the description of the drawings in the specification are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be

removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The disclosure is objected to because of the following informalities: On page 24 of the specification, line 22 begins with a period.

On page 37 of the specification, line 6 discloses "PDL3" rather than "PLD3".

Appropriate correction is required.

The aforementioned instances of failure to comply are not intended as an exhaustive list of all such potential failures to comply in the instant application. Applicants are encouraged to thoroughly review the application to ensure that the entire application is free of typographical errors.

Claim Objections

Claim 8 is objected to because of the following informalities: Claim 8 recites "chronic renal insufficiency" twice. Appropriate correction is required.

Claim 2 is objected to because of the following informalities: It appears that applicant inadvertently omitted "a" between "of" and "gene" in claim 2. Appropriate correction is required.

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 60/520,935, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. Application '935 does not

teach a limitation wherein expression of phospholipase D3 (PLD3) is down-regulated by at least 50% as compared to a control, as recited in instant claim 2; and does not teach that the fibrosis related pathology is ocular scarring or cataract, as required by instant claim 9.

Therefore, claims 2 and 9 are accorded an effective filing date of 11/16/04, the filing date of application PCT/IL04/01049, the earliest filed document to support the claim limitations.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 5, 6, 8, and 9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims are directed to a method of treating any fibrosis-related pathology in a subject which comprises administering to the subject a therapeutically effective amount of a pharmaceutical composition comprising any Phospholipase D3 inhibitor directed to any Phospholipase D3 sequence so as to thereby treat the subject.

The instant rejection is three-fold: 1) the specification does not describe a sufficient species of inhibitors of PLD3 to describe the genus that is embraced by the instant method; 2) the specification does not describe PLD3 in a manner that would allow the skilled artisan to envision the genus of target sequences; and 3) the specification does not describe the genus of fibrosis-related pathologies in a manner to allow the skilled artisan to envision the genus of disorders to be treated by the instant method.

Regarding the genus of Phospholipase D3 sequences being targeted within the instant method, the claims do not recite a specific PLD3 nucleotide sequence by SEQ ID NO, but rather refer to the broad genus of PLD3 sequences. The claims encompass a method of introducing any type of PLD3 inhibitor to inhibit the expression of any PLD3sequence, as well as encompass targeting any PLD3 homolog or allelic variant from any species known or yet to be discovered of PLD3, as well as DNA genomic fragments, spliced variants or fragment that retains PLD3-like activity. Furthermore, the specification discloses that any full-length sequence or fragment or domain thereof is included in the instant genus (see page 10).

Furthermore, although the specification discloses inhibitory agents that are specific for a specific PLD3 sequence, the specification does not describe such agents directed to any other species of PLD3 to describe the instantly claimed genus of targeting any PLD3. Each of the instantly disclosed agents is targeted to a single sequence, although the claims are drawn to a huge genus of possible PLD3 sequences. One of ordinary skill in the art could not make such agents to any PLD3 without

knowledge of the sequences that are embraced by the instant genus. Given the breadth of sequences embraced in the instantly claimed genus, one could not envision the member agents that target such a broad genus of possible sequences.

Regarding the genus of inhibitory agents, the specification discloses that the genus includes any small chemical molecule, antibodies, antisense DNA or RNA molecules, siRNA, proteins, polypeptides, and peptides (see page 10). Although the specification discloses some inhibitory molecules, the specification does not describe an adequate species of inhibitory molecules to demonstrate that applicant was in possession of the claimed molecules within the instant method at the time the invention was made. The instant genus of inhibitory molecules is very large, including aptamers, triplexes, and miRNAs, for example.

Not only is applicant claiming a method of inhibiting any PLD3 with any type of inhibitor, but is also claiming to treat any fibrosis-related pathology with the instant method. Applicant has not set forth a criteria or structural characteristic to define the genus of pathologies that are “fibrosis-related” in order for one of skill to be able to envision the pathologies of the instant genus. The instant claims embrace treating any pathology with any type of relation to fibrosis.

Therefore, the scope of the claimed invention is broad and the skilled artisan would not be able to envisage the entire genus claimed of agents that inhibit the expression of any PLD3 and treat any pathology with any relation to any fibrosis such that the skilled artisan would recognize that the applicant was in possession of the claimed genus at the time of filing.

Claims 1, 2, 5, 6, 8, and 9 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of inhibiting PLD3 expression in a cell *in vitro* via introducing a PLD3 siRNA molecule or a method of delivering a PLD3 siRNA directly to the target *in vivo*, does not reasonably provide enablement for a method of delivering any inhibitory agent via any means of delivery in a subject with the resultant treatment of any fibrosis-related pathology. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. Specifically, the claims encompass *in vivo* effects that are not enabled.

Factors to be considered in a determination of lack of enablement include, but are not limited to:

(A) The breadth of the claims;

(B) The nature of the invention;

(C) The state of the prior art;

(D) The level of one of ordinary skill;

(E) The level of predictability in the art;

(F) The amount of direction provided by the inventor;

(G) The existence of working examples; and

(H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)

The instant claims are directed to a method of treating any fibrosis-related pathology in a subject which comprises administering to the subject a therapeutically effective amount of a pharmaceutical composition comprising any Phospholipase D3 inhibitor so as to thereby treat the subject, wherein the inhibitor is delivered via any means; wherein the inhibitor is a Phospholipase D3 siRNA, and to treatment of specific fibrosis-related pathologies.

The specification discloses *in situ* hybridization analysis of PLD3 expression in rat liver fibrosis with resultant increase in the number of mesenchymal and inflammatory cells expressing PLD3 (see page 39). However, the specification does not draw a nexus between inhibition of expression of PLD3 and treatment of any fibrosis-related pathology or with the specific pathologies of claims 8 and 9. Pathologies are multi-factorial and the instant specification does not demonstrate that inhibition of PLD3 would result in treatment of any of the instant pathologies and certainly has not demonstrated that inhibition of PLD3 would result in the treatment of any fibrosis-related pathology, embracing those that do not even necessarily have any relationship with PLD3 expression.

Furthermore, the claims require successful delivery of any PLD3 inhibitor in order to result in inhibition of the PLD3 target. The *in vivo* teachings of the specification regarding delivery of inhibitors and resultant inhibition of PLD3 or treatment effects are strictly prophetic. The state of the art has exemplified that PLD3 can be successfully knocked down in vitro with PLD3 siRNA molecules with resultant inhibition of the survival of cancer cells, as evidenced by the teachings of Hu et al. (US 2007/0087984

A1). These teachings are enabling for direct delivery of PLD3 siRNA molecules in vivo to inhibit cancer cell growth, but is not enabling for broad methods of treatment of the instantly recited pathologies with any inhibitory molecule delivered via any means, embracing systemic delivery with the instantly recited outcomes.

For example, there is no guidance in the specification as filed that teaches how to broadly deliver a siRNA and mediate RNA interference *in vivo* with the resultant treatment effects. Although the state of the art has demonstrated RNA interference with siRNA molecules targeting PLD3 *in vitro*, applicant is not enabled for mediating RNA interference *in vivo* by the broadly recited methods, as delivery is known in the art to be unpredictable with regards to dsRNA duplexes.

The references cited herein illustrate the state of the art for therapeutic *in vivo* applications using dsRNA. Scherer et al. (Nat. Biotechnol., 2003, 21(12), pages 1457-1465) teach that antisense oligonucleotides (ODNs), ribozymes, DNAzymes and RNA interference (RNAi) each face remarkably similar problems for effective application: efficient delivery, enhanced stability, minimization of off-target effects and identification of sensitive sites in the target RNAs. Scherer et al. teach that these challenges have been in existence from the first attempts to use antisense research tools, and need to be met before any antisense molecule can become widely accepted as a therapeutic agent.

Mahato et al. (Expert Opinion on Drug Delivery, January 2005, Vol. 2, No. 1, pages 3-28) teach that antisense oligodeoxynucleotides and double-stranded small interfering RNAs have great potential for the treatment of many severe and debilitating

diseases. Mahato et al. teach that efforts have made significant progress in turning these nucleic acid drugs into therapeutics, and there is already one FDA-approved antisense drug in the clinic. Mahato et al. teach that despite the success of one product and several other ongoing clinical trials, challenges still exist in their stability, cellular uptake, disposition, site-specific delivery and therapeutic efficacy. Mahato et al. teach that in order for siRNAs to be used as therapeutic molecules several problems have to be overcome, including: the selection of the best sequence-specific siRNA for the gene to be targeted and the ability to minimize degradation in the body fluids and tissues.

Zhang et al. (Current Pharmaceutical Biotechnology 2004, vol. 5, p.1-7) reviews the state of the art with regard to RNAi and has this to say about use in mammalian cells. "Use of siRNA in mammalian cells could be just as far-reaching, with the applications extending to functional genomics and therapeutics. But various technical issues must be addressed, especially for large-scale applications. For instance, dsRNA can be delivered to *C. elegans* by feeding or soaking, but effective delivery of siRNAs to mammalian cells will not be so simple."

As outlined above, it is well known that there is a high level of unpredictability in the RNAi art for therapeutic *in vivo* applications. The scope of the claims in view of the specification as filed together do not reconcile the unpredictability in the art to enable one of skill in the art to make and/or use the claimed invention, namely a broad method of mediating RNA interference encompassing *in vivo* treatment effects.

MPEP 2164.01
Any analysis of whether a particular claim is supported by the disclosure in an application requires a determination of whether that disclosure, **when filed**, contained sufficient information regarding the

subject matter of the claims as to enable one skilled in the pertinent art to make and use the claimed invention.

Also, MPEP 2164.01(a)
A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, **at the time the application was filed**, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. In re Wright, 999 F.2d 1557,1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993).

Given the teachings of the specification as discussed above, one skilled in the art could not predict *a priori* whether introduction of a PLD3 siRNA *in vivo* by the broadly disclosed methodologies of the instantly claimed invention, would result in successful RNA interference or treatment of the instant breadth of pathologies. Without further guidance, one of skill in the art would have to practice a substantial amount of trial and error experimentation, an amount considered undue and not routine, to practice the instantly claimed invention.

A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, **at the time the application was filed**, would not have taught one skilled in the art how to make and/or use the **full scope** of the claimed invention without undue experimentation (see MPEP 2164.01(a)).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section

> 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 5, 6, and 8 are rejected under 35 U.S.C. 102(e) as being anticipated by Hu et al. (US 2007/0087984 A1).

The instant claims are directed to a method of treating a fibrosis-related pathology in a subject which comprises administering to the subject a therapeutically effective amount of a pharmaceutical composition comprising a Phospholipase D3 inhibitor so as to thereby treat the subject; wherein the composition comprising an oligoribonucleotide that down-regulates expression of Phospholipase D3 gene expression by at least 50% as compared to a control; wherein the inhibitor is a Phospholipase D3 siRNA. The claims are further directed to a vector comprising a nucleic acid molecule encoding the siRNA and specify fibrosis-related pathologies.

Hu et al. teach a method of increasing inhibition of cancer cells comprising introducing into the cell an effective amount of an expression vector comprising a sequence of nucleotides that encodes a ribozyme having a disclosed substrate binding sequence or a siRNA, wherein the expression vector is preferably administered in combination with a suitable carrier. Hu et al. teach that once the vector is administered, the ribozyme or siRNA is expressed in the cell (see paragraph [0173]). Hu et al. teach that the method can be applied to a subject with cancer and that the vector can be administered to the subject with a variety of non-toxic pharmaceutically acceptable carriers (see paragraph [0174]).

Hu et al. teach knockdown of PLD3 and resultant inhibition of the survival of cancer cells and sets forth the specific PLD3 target sequence as GenBank Accession #

NM_012268 (see paragraph [0230]). Hu et al. teach that PLD3 appears to be predominantly of neuronal origin and is overexpressed in cancers including colon, kidney, stomach, and lung cancers (see paragraph [0232]).

Hu et al. teaches construction of siRNAs targeting PLD3 (see paragraphs [0233]-[0234]) and exemplifies transfection of PLD3 siRNAs into A172 glioblastoma cells with resultant PLD3 knockdown and reduction in cancer cell survival (see paragraphs [0235]-[0237]). Hu et al. teaches that PLD3 siRNAs result in over 50% inhibition of PLD3 expression when compared to a control (see Figure 20B, siRNA A and D).

It is noted that the *in vitro* data of Hu et al. is enabling for direct *in vivo* delivery of the siRNA to the target to inhibit PLD3 expression and treatment of glioblastoma, as explained in the rejection under 35 USC 112, 1st paragraph (scope of enablement) above. The instant rejection is based upon the teachings of Hu et al. which anticipate the instant claims. However, Hu et al. is considered as enabled as the instant claims.

The instant specification defines fibrosis-related pathologies to include cancer (see page 9). Therefore, the method of treating a cancer of Hu et al., more specifically kidney cancer, via administering a Phospholipase D3 siRNA meets the instant limitation of treating a fibrosis-related pathology or more specifically kidney fibrosis.

Therefore, the instant claims are anticipated by Hu et al.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AMY BOWMAN whose telephone number is (571)272-0755. The examiner can normally be reached on Monday-Thursday 6:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Doug) Schultz can be reached on (571) 272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AMY BOWMAN
Examiner
Art Unit 1635

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